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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/058,122	01/29/2002	Philip B. Sample	00167-455001	3500
7590 JOEL R. PETROW Smith & Nephew, Inc. 1450 Brooks Road Memphis, TN 38116			EXAMINER SHAFFER, RICHARD R	
			ART UNIT 3733	PAPER NUMBER
			MAIL DATE 12/21/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/058,122	Applicant(s) SAMPLE, PHILIP B.	
	Examiner Richard R. Shaffer	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26, 37, 38, 41-75 and 77-82 is/are pending in the application.
- 4a) Of the above claim(s) 4, 7-10, 20, 22 and 38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5, 6, 11-19, 21, 23-26, 37, 41-75 and 77-82 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 20th, 2007 has been entered.

Claim Rejections - 35 USC § 112

Applicant's amendment to claim 72 is acknowledged and accepted by the examiner. The previous 35 U.S.C. 112, first paragraph rejection is hereby withdrawn in regard to claims 72-75.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 43, 47-71, 73, 78 and 79 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 43 and 47 recite the limitation, "the off-axis movement **alone** being capable of **acting to cut tissue**." The off-axis movement is not the only force causing

cutting of the tissue. For example, one would have to hold the device against tissue. Applicant further repeatedly states how the device must shear the tissue between the cutter and a surface of the instrument, etc. Therefore, it is clear it is "not alone" and is merely one of several components involved in cutting tissue.

All dependent claims of 43 and 47 are rejected for containing new matter through dependency.

Claim 73 (after amendment of claim 72) recites, "...the cutter comprises a hollow body, **the body defining an opening therethrough.**" Claim 72 as amended already states, "the cutter defining a through bore..." Applicant does not have support for the cutter defining two bores/openings as required by claim 73.

Claim 79 recites, "...wherein a maximum tangential speed of the cutter is at a center of cutting action." There is no support in the specification as originally filed to support this limitation.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3, 5, 6, 11-19, 21, 23-26, 37, 41-71 and 77-79 are rejected under 35 U.S.C. 102(b) as being anticipated by Hamlin et al (WO 92/08416).

Hamlin et al disclose (**Figures 3-12**) a cutting instrument comprising: an outer member (**46, 30 and 22 together**) having a spherical terminal end housing a cutter (**62**); the cutter comprises a spherical portion; the terminal end further defines an opening (**50**); the cutter (**62**) having an opening (**64**) and a circumferentially located plurality of teeth (**66**); the outer member includes a first and second arc-shaped chambers to receive shafts (enlarge portion **56** is the second shaft and the portion containing the plurality of teeth is the first shaft) of the cutter (**62**); an inner member (**70**) having a hollow passage capable of removing cut tissue through it; the inner member having a plurality of teeth (**78**) for engaging the teeth (**66**) at a perpendicular angle (**Page 3, Lines 28-33**); and the inner member will rotate about a fixed axis causing the cutter to rotate about a perpendicular axis. The device of Hamlin et al is inherently capable of performing the intended functions of applicant's claimed device as well as anticipating applicant's product-by-process claims since applicant must make a showing that one would not be able to form the device of Hamlin et al in the manners claimed to overcome anticipation.

Claims 37, 41, 47-57, 61-75, 77, 78, 81 and 82 rejected under 35 U.S.C. 102(e) as being anticipated by Michelson (US Patent Application Publication 2002/0058944).

Michelson discloses (**Figures 1B-15**) a cutting instrument comprising: an outer member (**160**) having a spherical (**curvature on 170, 172 or 174**) terminal end housing a cutter (**116 and 132 together**); the cutter comprises a spherical portion (portions of **122 or 138**); the terminal end further defines an opening (**168**); the cutter being a hollow body (due to the depressions surrounding **122 or 138** relative to the rest of the cutter); the hollows of the cutter defining a through-bore/passage (within the outer member); the cutter having two shafts (**144 and 146**) protruding from first and second portions of the cutter 180 degrees apart; each shaft having a plurality of circumferentially located teeth; an inner member (**140**) defining a passage (within **126**) capable of removing tissue; the inner member having a plurality of teeth (**142**) for directly engaging the teeth of the shafts perpendicularly; and the inner member will rotate about a fixed axis causing the cutter to rotate about a perpendicular axis. The device of Michelson is inherently capable of performing the intended functions of applicant's claimed device as well as anticipating applicant's product-by-process claims since applicant must make a showing that one would not be able to form the device in the manners claimed to overcome anticipation. It is also noted that the cutter of Michelson is not required to be straight, but can be angled or shaped in a concave/convex manner.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 5, 6, 14-19, 21, 23-26, 42-46, 79 and 80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Michelson in view of Reiley et al (US Patent 6,440,138).

Michelson discloses all of the claimed limitations except for the inner member having an inner passage. Reiley et al teach an inner member (40) having a passage (128) for allowing a rinsing fluid as well as removing cancellous bone cut by the device. It would have been obvious to one having ordinary skill in the art at the time of invention to provide for a passageway in the inner member of Michelson in order to allow for irrigation and/or suction which is well known in the surgical art for allowing a surgeon to visualize the area being treated.

Response to Arguments

Applicant's arguments filed on November 20th, 2007 have been fully considered but they are not persuasive.

In regard to applicant's arguments over the 35 U.S.C. 112, first paragraph, applicant's arguments are not what is found in the claim. The claims currently state "...the off-axis movement alone being capable of acting to cut tissue." This does not mean it is the only movement causing cutting, it is stating it is the only action period.

Further, it is still not felt that applicant has support for the argued limitation since such can not be reasonably deemed inherent from the disclosure as originally filed.

In regard to the anticipation rejections of independent claims:

1) The outer member of Hamlin et al does "restrain" the cutter from following rotation of the inner member due to the rigid construct preventing the device from aligning.

37) The cutter does extend distal of the terminal end since the terminal end can be construed as the slanted edge to which the cutter is exposed.

47) An edge of the cutter does intersect "an axis" of rotation. They are orientated at an angle relative to one another, further, any axis can be deemed an "axis" of rotation.

72) Moot, due to the new grounds of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard R. Shaffer whose telephone number is 571-272-8683. The examiner can normally be reached on Monday-Friday (7am-5pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Richard Shaffer
December 14th, 2007

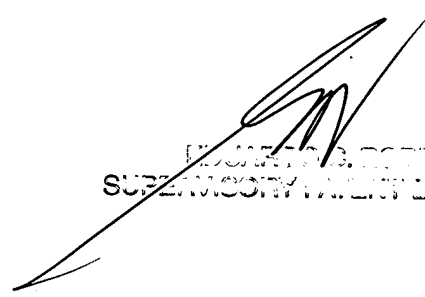


EXHIBIT 100
SUPERVISOR/INVENTOR/EXAMINER